OBJECTIVES: To estimate the budget impact of adding omalizumab to standard therapy (ST) in patients with uncontrolled severe allergic asthma, from the perspective of the Brazilian private health care system, over a 5-year time horizon (GOLD stage III or IV). A budget impact model was developed to estimate the budget impact for Brazil, based on local epidemiological and drug cost data. The eligible population was based on the following inputs: 2013 population estimate (age ≥ 18 years), prevalence of diagnosis: 10% proportion of patients diagnosed and receiving treatment: 6.5%; percentage with allergic asthma: 69%; percentage with immunoglobulin E (IgE) ≥30 IU/mL: 78.7%; percentage with uncontrolled, severe disease: 2.4%; proportion of population using the private health care system: 25.1%. For the following years, an annual population growth rate of 1.17% was assumed. Average doses, resource utilization per exacerbation and proportion of patients who respond to omalizumab treatment were derived from the INNOVATE trial. Direct costs of the omalizumab purchase and the costs of health care consumption related to exacerbations and routine visits. These costs were calculated from the perspective of the health care system and medications: 25.1%. For the following years, an annual percentage with immunoglobulin E (IgE) ≥30 IU/mL: 78.7%; percentage with allergic asthma: 69%; percentage with diagnosed and receiving treatment: 6.5%; percentage with allergic asthma: 69%; percentage with diagnosed and receiving treatment: 6.5%. For the following years, an annual percentage with allergic asthma: 69%; percentage with diagnosed and receiving treatment: 6.5%. For the following years, an annual percentage with allergic asthma: 69%; percentage with diagnosed and receiving treatment: 6.5..

RESULTS: The number of patients eligible for add-on omalizumab therapy that met the eligibility criteria was estimated to be around 3,887 in the first year. The annual budget impact of omalizumab was approximately BRL25 million. BRL50 million. BRL77 million. BRL104 million and BRL131 million for years 1 to 5, respectively. RESULTS: The number of patients eligible for omalizumab therapy (ST) in patients with severe allergic asthma, from the perspective of the Brazilian private health care system was approximately BRL25 million. BRL50 million. BRL77 million. BRL104 million and BRL131 million for years 1 to 5, respectively. RESULTS: The number of patients eligible for add-on omalizumab therapy that met the eligibility criteria was estimated to be around 3,887 in the first year. The annual budget impact of omalizumab was approximately BRL25 mill.